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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,481	06/30/2004	Michael Petersen	604-052	4498

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EXAMINER	
TWEEL JR, JOHN ALEXANDER	
ART UNIT	PAPER NUMBER
2636	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,481	PETERSEN ET AL.	
	Examiner	Art Unit	
	John A. Tweel, Jr.	2636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,25-27 and 31-34* is/are pending in the application.

4a) Of the above claim(s) *7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-12 and 25-27* is/are rejected.

7)☒ Claim(s) *31-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/30/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *12/11/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-6, 10-12, 25-27, and 31-34, drawn to medication event alerting, classified in class 340, subclass 590.

   II. Claims 7-9, drawn to circuit manufacture, classified in class 206, subclass 528.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the material does not have to be in a roll form for circuit application. Large sheets of the frangible backing material may also be used.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jennifer Yancy on 12/8/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 10-12, 25-27, and 31-34. Applicant in replying to this Office action must make affirmation of this election. Claims 7-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Gordon** [U.S. 4,617,557] (supplied by applicant).

For claim 1, the replicate for application to a blister package taught by **Gordon** includes the following claimed subject matter, as noted, 1) the claimed blister package containing a plurality of articles in an individual blister is seen in Figure 3 as the

package (No. 48) through which medication is projected through a corresponding portion of the package, 2) the claimed frangible backing sheet is met by the backing layer (No. 52), 3) the claimed integrated circuit is met by the electronic circuitry contained in the housing (No. 60), 4) the claimed plurality of conductive traces is met by the conducting pathways (No. 54) on the backing layer, each of which is connected to the integrated circuit, 5) the claimed power source is met by the battery (No. 20), and 6) the claimed means for attaching the replicate to the package is met by the adhesive substance (No. 50) that attaches the device to the blister package, each of the traces are designed to be positioned on the backing sheet to intersect a corresponding one of the blisters when the device is attached to the package, whereby when an article is projected from its blister through the replicate the trace is broken to define an event that is recorded by the circuit, as seen in claim 1 with its scanning and memory means.

For claim 5, the device of **Gordon** includes an adhesive substance (No. 50) applied to the backing sheet for attachment to the blister package.

For claim 10, the blister package taught by **Gordon** includes the following claimed subject matter, as noted, 1) the claimed blister package having a sheet of material, a plurality of individual flexible blisters, an article located in each blister, and a closure seal formed of frangible material is seen in Figure 3 as the package (No. 48) through which medication is projected through a corresponding portion of the package, as described in the specification as those typically provided by pharmaceutical companies, 2) the claimed frangible backing sheet is met by the backing layer (No. 52), 3) the claimed integrated circuit is met by the electronic circuitry contained in the

housing (No. 60), 4) the claimed plurality of conductive traces is met by the conducting pathways (No. 54) on the backing layer, each of which is connected to the integrated circuit, 5) the claimed power source is met by the battery (No. 20), and 6) the claimed means for attaching the replicate to the package is met by the adhesive substance (No. 50) that attaches the device to the blister package, each of the traces are designed to be positioned on the backing sheet to intersect a corresponding one of the blisters when the device is attached to the package, whereby when an article is projected from its blister through the replicate the trace is broken to define an event that is recorded by the circuit, as seen in claim 1 with its scanning and memory means.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-4, 6, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gordon** in view of **Niemiec et al** [U.S. 6,411,567].

For claim 2, the replicate taught by **Gordon** includes the claimed subject matter as discussed in the rejection of claim 1 above. However, there is no mention of recording the time associated with the event for retrieval at a later point in time.

The drug delivery management system taught by Niemiec includes an embodiment wherein a memory records the time at which a certain medication cell was

accessed. The obvious advantages of this system is to improve the safety, compliance and cost of prescription drugs in the hospital and at home as well as improve the ability of the pharmaceutical industry to acquire information regarding the real world usage of medications.

Any information that reveals the timetable of usage of medication is helpful to insure that medication schemes are being followed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a time associated with the event to be recorded in a memory for retrieval into the system of Gordon for the purpose of insuring the proper medication regimen.

For claim 3, the power supplies of both references are integral with their respective integrated circuits.

For claim 4, the traces found in **Niemiec** are printed on the backing sheet.

For claim 6, the device of **Niemiec** includes a cover sheet (No. 104) applied to the replicate with the conductive traces between it and the backing sheet.

For claim 11, the blister package taught by **Gordon** includes the following claimed subject matter, as noted, 1) the claimed blister package having a sheet of material, a plurality of individual flexible blisters, an article located in each blister, and a closure seal formed of frangible material is seen in Figure 3 as the package (No. 48) through which medication is projected through a corresponding portion of the package, as described in the specification as those typically provided by pharmaceutical companies, 2) the claimed frangible backing sheet is met by the backing layer (No. 52), 3) the claimed integrated circuit is met by the electronic circuitry contained in the

housing (No. 60), 4) the claimed plurality of conductive traces is met by the conducting pathways (No. 54) on the backing layer, each of which is connected to the integrated circuit, 5) the claimed power source is met by the battery (No. 20), and 6) the claimed means for attaching the replicate to the package is met by the adhesive substance (No. 50) that attaches the device to the blister package, each of the traces are designed to be positioned on the backing sheet to intersect a corresponding one of the blisters when the device is attached to the package, whereby when an article is projected from its blister through the replicate the trace is broken to define an event that is recorded by the circuit, as seen in claim 1 with its scanning and memory means. However, the replicate is not attached to the same surface as the flexible blisters.

The conductive traces found in **Niemiec** are attached to the same side as the flexible blisters in relation to their position of the scored cover (No. 104). This reference is plain evidence that the circuitry with traces may be secured to either side of the cover sheet and have the same outcome. As this does not produce any new or unexpected result, it is considered an obvious variation on the prior art.

For claim 12, the device of **Niemiec** includes a cover sheet (No. 104) applied to the replicate with the conductive traces between it and the backing sheet.

10. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gordon**.

For claim 25, the blister package taught by **Gordon** includes the following claimed subject matter, as noted, 1) the claimed blister package having a sheet of

material, a plurality of individual flexible blisters, an article located in each blister, and a closure seal formed of frangible material is seen in Figure 3 as the package (No. 48) through which medication is projected through a corresponding portion of the package, as described in the specification as those typically provided by pharmaceutical companies, 2) the claimed frangible backing sheet is met by the backing layer (No. 52), 3) the claimed integrated circuit is met by the electronic circuitry contained in the housing (No. 60), 4) the claimed plurality of conductive traces is met by the conducting pathways (No. 54) on the backing layer, each of which is connected to the integrated circuit, 5) the claimed power source is met by the battery (No. 20), and 6) the claimed means for attaching the replicate to the package is met by the adhesive substance (No. 50) that attaches the device to the blister package, each of the traces are designed to be positioned on the backing sheet to intersect a corresponding one of the blisters when the device is attached to the package, whereby when an article is projected from its blister through the replicate the trace is broken to define an event that is recorded by the circuit, as seen in claim 1 with its scanning and memory means. However, there is no mention of a first flap, second flap, and a spine hingedly attached to the two flaps wherein the replicate is attached to the second flap.

The Examiner himself has been prescribed medication that was packaged exactly in this form, complete with openings in one flap corresponding to the blisters they were positioned opposite. As this is considered a well known and common form of medication packaging, it is judged an obvious variation on the prior art and therefore not a patentable innovation.

For claims 26 and 27, the location of the integrated circuit is not considered a patentable innovation as the location of the circuit does not result in any new or unexpected result and is a matter best left to the designer or user of the invention to best utilize the product.

11. Claims 31-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter:

The prior art does not show a blister package having conductive traces that define a pattern of intersecting sets of parallel traces, said traces positioned on the backing sheet so that more than one thereof will intersect each of the blisters when the replicate is attached to the package. This is considered unobvious when compared to the prior art.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Simons [U.S. 4,711,368] determines whether or not a package has been opened or tampered with.

Eckernas et al [U.S. 5,072,430] signals the ingestion of medication wherein a blister package includes a grid of conductive cells.

Zeiter et al [U.S. 5,871,831] contains conductive strips opposite blister packs.

Niemiec [U.S. 6,574,166] is related to the above secondary reference.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Tweel, Jr. whose telephone number is 571 272 2969. The examiner can normally be reached on M-F 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Hofsass can be reached on 571 272 2981. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JAT
12/11/05

JOHN TWEEL
PRIMARY EXAMINER